



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Julie Breeden-Alemi, DVM

From: Eric Bohnenblust, Ph.D. Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Entomologist

Date: July 5, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: N/A / N/A / 392363

Decision no.: N/A / N/A / N/A

Submission no: N/A / N/A / N/A

Action code: Re-registration

Product Name: Thermacell Mosquito Repellent/Thermacell Mosquito Repellent with Earth Scent/Thermacell Mosquito Repellent Candle Lantern

EPA Reg. No or File Symbol: 71910-2/71910-3/71910-4

Formulation Type: Spatial Repellents

Ingredients statement from the labels with PC codes included:

d-Allethrin 21.97% PC: 004005

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): One appliance per 225 square feet

Use Patterns: Outdoor spatial repellents to repel insects including mosquitoes and black flies. Do not use indoors or in tents.

I. Action Requested: To satisfy the product specific data call-in (PDCI, PDCI-004005-27316) for reregistration of allethrin, the registrant submitted three studies for review to support efficacy claims against the public health pests including mosquitoes and black flies listed on the product labels for EPA Reg. Nos. 71910-2, 71910-3, 71910-4.

II. Background: For EPA Reg. No. 71910-2, the registrant has since submitted additional data and information to support repellency claims against mosquitoes (DPs 421168, 432851). The registrant has not submitted additional data to support public health pests for EPA Reg. Nos. 71910-3 or 71910-4. The three studies submitted to satisfy the PDCI for reregistration were also submitted and reviewed (DP 340719) by EPA as a condition of registration for EPA Reg. No. 71910-2. Conclusions for each MRID from the previous review are presented below.

III. MRID Summary:

47142402. ThermaCell® Area Repellent Field Test Report.

Conclusion: Unacceptable. This study is not acceptable to support product efficacy for EPA Reg. No. 71910-2,

71910-3, or 71910-4 because it does not meet the Agency's ethical standards per the associated ethics review dated May 5, 2016. From the science perspective, this study was conducted on a smaller area (176 ft²) than listed on the product label (225 ft²). Also, the study does not state how long the product was tested; current label claims for the mats specify four hours of protection time. Additionally, the study only tested one genera of mosquitoes.

47142403. ThermaCell® Area Repellent Field Test Report.

Conclusion: Extraneous. This MRID does not support efficacy claims this product because it was withdrawn from consideration for supporting efficacy claims for all three products (EPA Reg. Nos. 71910-2, 71910-3, 71910-4).

47142404. ThermaCell® Area Repellent Field Test Report.

Conclusion: Unacceptable. This study does not support repellency claims against black flies because repellency did not reach 75% and in many cases was not significantly different from the control. While repellency of *P. hirtipes* did reach 75% the number individuals of this species was about 20% of the overall number of black flies. Because the study did not parse the number individuals for each species, we cannot adequately evaluate whether the repellency provided against *P. hirtipes* is meaningful. Further, the statistical analyses as provided are inappropriate for the study; a more complex model should have been used which could account for effects based on direction and distance from the appliance.

IV. EXECUTIVE DATA SUMMARY:

(A) The data submitted above do not support product efficacy or any claims against mosquitoes, sand flies, or black flies or any other public health pests for any of the products.

V. LABEL RECOMMENDATIONS:

For EPA Reg. No. 71910-2: Please see comments in efficacy review associated with DP 340719.

For EPA Reg. No. 71910-3:

(1) All references to all public health pests must be deleted from the label.

(2) The following marketing claims are acceptable: N/A

(3) The following marketing claims are unacceptable: All marketing claims listing public health pests (mosquitoes and black flies). Claims listing "other [outdoor] flying insects" would need to be changed to indicate the specific pest if non-public health pests are included in this heading otherwise these claims must be deleted. The term "other flying insects" is also unacceptable because it is non-specific.

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: 47142402, 47142403, 47142404

(5) Note to PM/Reviewer: There are no data to support efficacy of this product currently on file with the Agency.

For EPA Reg. No. 71910-4:

(1) All references to all public health pests must be deleted from the label.

(2) The following marketing claims are acceptable: N/A

(3) The following marketing claims are unacceptable: All marketing claims listing public health pests (mosquitoes and black flies). Claims listing "other [outdoor] flying insects" would need to be changed to indicate the specific pest if non-public health pests are included in this heading, otherwise these claims must be deleted. The term "other flying insects" is also unacceptable because it is non-specific.

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to

support the product: 47142402, 47142403, 47142404

(5) Note to PM/Reviewer: There are no data to support efficacy of this product currently on file with the Agency.